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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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VISTA IP LAW GROUP LLP
12930 Saratoga Avenue
Suite D-2
Saratoga, CA 95070

EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/625,196

Applicant(s)

GUGLIELMI ET AL.

Examiner

Diane Yabut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 1-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2003 and 24 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/8/2003; 10/22/2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-28, drawn to a method for positioning an implant in a body, classified in class, subclass 213.
 - II. Claims 29-66, drawn to a system for positioning an implant in a body, classified in class 606, subclass 41.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used in a body lumen other than the vascular cavity.
3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.
4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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5. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

6. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. During a telephone conversation with David Burse on Friday, October 6, 2006 a provisional election was made without traverse to prosecute the invention of Group II directed towards Claims 29-66. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-29, which are directed towards Group I, are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

9. The information disclosure statements (IDS) submitted on 8 October 2003 and 22 October 2004 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 29-36, 44-46, 53-55, 57-62, and 64-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheldrup et al., or **Scheldrup** (U.S. Patent No. **5,669,905**).

Claim 29: Scheldrup discloses a catheter **158** having a proximal end and a distal end, the catheter being capable of being inserted into a vascular cavity in the body, a delivery member **102**, a temporary connection **106** joining an implant and a distal end of the delivery member, and an electrical measurement device, and when the delivery member, the temporary connection, and the implant are being advanced through the catheter, the electrical measuring device monitors an electrical condition related to a position of the temporary connection in the catheter, the electrical condition changing

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when the temporary connection reaches a predetermined location (Figures 3-5, and col. 4, lines 1-24 and col. 6, lines 36-62 and col. 7, lines 39-48).

Claims 30-31: Scheldrup discloses the delivery member comprising a delivery wire, or a tubular body **102** (Figure 3).

Claim 32: Scheldrup discloses the temporary connection comprising an electrolytic connection (col. 4, lines 34-42).

Claim 33: Scheldrup discloses a power supply **170**, the electrolytic connection being broken by current provided by the power supply through the delivery member and the temporary connection, the current corroding a portion of the temporary connection (Figures 4-5, and col. 4, lines 1-24).

Claim 34: Scheldrup discloses the portion of the temporary connection being corroded comprising a stainless steel portion of the delivery member that is exposed to blood in the vascular cavity (col. 5, lines 49-55).

Claims 35-36: Scheldrup discloses the electrical monitoring device **300** being included in the power supply and separate from the voltage supply (Figures 6-7 and col. 5, lines 1-3).

Claims 44-45: Scheldrup discloses the implant comprising a vaso-occlusive implant, which also comprises a coil (col. 1, lines 1-19 and col. 6, lines 1-11).

Claim 46: Scheldrup discloses the coil comprising a Guglielmi Detachable Coil (GDC) (col. 12, lines 19-33).

Claims 53-55: Scheldrup discloses the electrical measurement device generating an output signal comprising an audio signal in response to the changed electrical condition

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(col. 10, lines 30-44). Although Scheldrup does not disclose the output signal comprising a visual signal, it would have been obvious to one of ordinary skill in the art to provide a visual signal, along with the audio signal of Scheldrup, such as a blinking light, since it was known in the art that prompting the surgeon or user of the device that the procedure is complete is beneficial, as well as a safety measure.

Claim 57: Scheldrup discloses the output signal being provided to a controller, the temporary connection being broken in response to the controller (Figure 6).

Claim 58: Scheldrup discloses insulative members **112** and **110** (Figure 2, col. 6, lines 1-22). Although Scheldrup does not disclose an insulation member between the implant and the temporary connection, it would have been obvious to one of ordinary skill in the art to provide an insulation member between the implant and the temporary connection to focus electrolysis on a targeted, specific location.

Claims 59-61: Scheldrup discloses the predetermined position comprising the distal end of the catheter and the electrical condition changing when the temporary connection reaches or exits the distal end of the catheter (col. 7, lines 20-48).

Claim 62: Scheldrup discloses the electrical measurement device comparing a reference current with a second current that is generated when the temporary connection reaches the predetermined location (Figure 11 and col. 11, lines 24-34).

Claims 64-65: Scheldrup discloses a conductive wire connected between the electrical measurement device and the distal end of the catheter, the conductive wire being inserted through the catheter, the electrical monitoring device detecting an electrical condition related to a position of the temporary connection in the catheter

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through the conductive wire, and the electrical monitoring device comprising a volt/current meter (Figures 4-6).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Scheldrup** (U.S. Patent No. **5,669,905**), as applied to Claim 29 above, and further in view of **Palermo** (U.S. Patent No. **5,250,071**).

Claim 37: Scheldrup discloses the claimed device as discussed above, except for the temporary connection comprising breaking a temporary mechanical connection.

Palermo teaches an embolic coil with a temporary connection comprising breaking a temporary mechanical connection (col. 2, lines 63-67 and col. 3, lines 1-18). It would have been obvious to one of ordinary skill in the art to provide a temporary mechanical connection, as taught by Palermo, to Scheldrup, since it was known in the art that temporary mechanical connections are common in detachable surgical implants that extend to filters and stents.

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14. Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scheldrup** (U.S. Patent No. **5,669,905**), as applied to Claim 29 above, and further in view of Guglielmi et al., or **Guglielmi** (U.S. Patent No. **5,569,245**).

Claims 38-39: Scheldrup discloses the claimed device, as discussed above, except for the temporary connection comprising a temporary connection that is broken by application of heat and radio frequency (RF) radiation.

Guglielmi teaches a temporary connection that is broken by application of heat and radio frequency (RF) radiation (col. 3, lines 10-20). It would have been obvious to one of ordinary skill in the art to provide a temporary connection broken by heat and RF radiation, as taught by Guglielmi, to Scheldrup, since it was known in the art that heat and RF radiation are effective detachment sources and commonly break connections, joints, or attachments in surgical devices.

15. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Scheldrup** (U.S. Patent No. **5,669,905**), as applied to Claim 29 above, and further in view of Sepetka et al, or **Sepetka** (U.S. Patent No. **5,814,062**).

Claim 40: Scheldrup discloses the claimed device as discussed above, except for the temporary connection comprising a temporary connection that is hydraulically broken.

Sepetka teaches a temporary connection that is hydraulically broken (col. 3, lines 10-26). It would have been obvious to one of ordinary skill in the art to provide a temporary connection that is hydraulically broken, as taught by Sepetka, to Scheldrup,

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since it was known in the art that fluid pressure is commonly used to disconnect temporary detachments between embolic coils and delivery members.

16. Claims 41-43 and 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scheldrup** (U.S. Patent No. **5,669,905**), as applied to Claim 29 above.

Claims 41-43: Scheldrup discloses the electrical condition comprising an impedance (col. 4, lines 1-24). Although Scheldrup does not disclose the electrical condition comprising a voltage or current, it would have been obvious to one of ordinary skill in the art to monitor either voltage or current, depending on the circuit, as both are measured and displayed in Figure 6 of Scheldrup.

Claims 47-50: Scheldrup discloses the coil including platinum (col. 5, lines 38-50). Although Scheldrup does not disclose the coil having a bio-reactive material coating or the coil being a non-bio-reactive polymer coil, it would have been obvious to one of ordinary skill in the art to provide the claimed materials, since it was known in the art that a coating of bio-reactive material may aid in the endovascular embolism or occlusion and non-bio-reactive polymer coils can remain longer within the body without having to be surgically removed.

Claims 51-52: Scheldrup discloses the claimed device except for the implant comprising a stent or a filter. It would have been obvious to one of ordinary skill in the art to provide a stent or a filter as the implant, since it was known in the art that vaso-occlusion is commonly achieved by filters and stents.

17. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Scheldrup** (U.S. Patent No. **5,669,905**), as applied to Claim 29 above, and further in view of Wheelock et al., or **Wheelock** (U.S. Patent No. **6,077,260**).

Claim 56: Scheldrup discloses the claimed device as discussed above, except for the output signal being provided to a user and the temporary connection being broken in response to user input.

Wheelock teaches the output signal being provided to a user and the temporary connection being broken in response to user input (col. 6, lines 52-67). It would have been obvious to one of ordinary skill in the art to provide the output signal being provided to a user and the temporary connection being broken in response to user input, as taught by Wheelock, to Scheldrup since it was known in the art that user input allows more control of the procedure and may avoid undesired reactions to occur.

18. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Scheldrup** (U.S. Patent No. **5,669,905**), as applied to Claim 29 above, and further in view of Cheng et al., or **Cheng** (U.S. Patent No. **6,296,636**).

Claim 63: Scheldrup discloses the claimed device as discussed above, except for the electrical measurement device including a comparison circuit that compares a threshold current to a current measured by the electrical measurement device, the comparison circuit generating an output indicating whether the temporary connection reaches a predetermined location.

Cheng teaches an electrical measurement device including a comparison circuit that compares a threshold current to a current measured by the electrical measurement device, the comparison circuit generating an output which would indicate whether the temporary connection reaches a predetermined location – the output indicating limiting power (col. 5, lines 15-34). Cheng teaches that limiting power during electrosurgery avoids overcurrents or sparks that may occur (col. 3, lines 48-55). It would have been obvious to one of ordinary skill in the art to provide an electrical measurement device including a comparison circuit that compares a threshold current to a current measured by the electrical measurement device, as taught by Cheng, to Scheldrup in order to obtain a desired output signal, which may limit power during electrosurgery to avoid overcurrents or sparks.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER